

JUN 10 2005

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<b>Date:</b>	June 10, 2005	<b>Pages:</b>	15 (including cover sheet)		
<b>Re:</b>	Application No. 09/627,796 Date Filed: July 28, 2000 Confirmation No. 3581 Title: Non-Nucleic Acid Probes, Probe Sets, Method and Kits Pertaining To The Detection Of Human Chromosomes X, Y, 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18 And 20 As Well As 13/21 As A Pair Our Ref No. BP9806US-CP2				

Attached is a Request for Consideration Petition Under 37 C.F.R. §1.144 or §1.181

Please send confirmation of receipt to fax no. 508-383-7468.

Should you have any questions, please contact me at 508-383-7682.

Thank you.

Pat Tocci  
IP Paralegal

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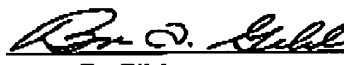
## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Serial No: 09/627,796 Confirmation No. 3581  
Date Filed: July 28, 2000  
Application Title: Non-Nucleic Acid Probes, Probe Sets, Method and Kits  
Pertaining To The Detection Of Human Chromosomes X, Y,  
1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18 And 20 As Well As  
13/21 As A Pair  
Applicant: Krishan L. Taneja  
Group Art Unit: 1634  
Examiner: Jehanne Souaya Sittou  
Application Status: Non-Final Action issued on April 29, 2005  
Action Type: Reply To The "Decision On Petition" dated April 12, 2005

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Certificate of Transmission:  
37 C.F.R. § 1.8

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office (Fax No. 703-872-9306) on this 10<sup>th</sup> day of June 2005.

  
Brian D. Gildea  
Reg. No. 39,995

Attention:, Director, Technology Center, 1600:

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Request For Reconsideration  
Petition Under 37 C.F.R. § 1.144 or § 1.181

Commissioner for Patents  
Dear Sir or Madam:

Preliminary Statement

In the above captioned application, the Examiner issued a restriction requirement in Office Action paper No. 9 (Office Action dated September 21, 2001). Applicant did enter traverse of the restriction requirement as well as make appropriate arguments and present a request for reconsideration, in reply to said Office Action, by submission dated January 18, 2002. Applicants did timely file a petition under 37 C.F.R. § 1.144 requesting review of the Examiner's decision by paper dated July 28, 2004 (the "Petition").

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Applicants received a Decision On Petition (the "Decision") dated April 12, 2005 wherein the Petition was DENIED.

In response, Applicants hereby petition for review of the Examiner's decision with regard to a restriction requirement as set forth in Office Action paper No. 9 as well as review of the Decision (copy attached).

**Argument In Support Of Request To Withdraw Restriction Requirement**

a) The Restriction Requirement is Based Solely on 35 U.S.C. § 121

In support of the restriction requirement the Examiner stated:

*"The inventions are distinct, each from the other because of the following reasons: Each group is directed to nucleic acid sequences that identify or detect a different human chromosome. Each of the sequences are structurally and functionally different from each other. That is structurally, the sequences comprise a different sequences of nucleotide bases, thus resulting in unique sequences. Functionally, the sequences are different in that they identify or detect different chromosomes. The methods of each group are also patentably distinct because the method for detecting chromosome X is different from the method of detecting chromosome Y in that the sequences required to detect each chromosome are different. Each chromosome is made up of different nucleic acid sequences that are patentably distinct from each other and require different nucleic acid sequences for their identification or detection.*

*By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).*

*Nucleotide sequences that detect different chromosomes are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141."*

(OA dated September 21, 2001 at page 5-6)

From the foregoing, it is unequivocal that the restriction requirement rests on "misjoinder of invention" under 35 U.S.C. § 121 and on no other basis. More

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specifically, the restriction requirement is not based upon "improper Markush grouping".

b) Reasoning and Conclusion of the Decision

The Decision reiterates that the present restriction requirement rests upon misjoinder of invention under 35 U.S.C. § 121. Specifically, the Decision states:

*A requirement for restriction was mailed to applicants on September 21, 2001, requiring the restriction of the 45 claims to one of eighteen inventions under 35 U.S.C. § 121. (Emphasis added)*

(Decision at page 1)

Although the reasoning of the Decision appears to confuse the concepts of "misjoinder of invention" under 35 U.S.C. § 121 with the use of "improper Markush grouping", there is no clear support in the arguments that restriction is improper in this case under 35 U.S.C. § 121. Furthermore, there is no specific argument that Applicant has used "improper Markush grouping". Consequently, the holding of the Decision is fatally flawed as well as being contrary to the holdings of *In re Weber*, 580 F.2d 455; 198 U.S.P.Q. 328 (CCPA, 1978), *In re Haas*, 580 F.2d 461; 198 U.S.P.Q. 334 (CCPA, 1978), *In re Harnisch*, 631 F.2d 716; 206 U.S.P.Q. 300 (CCPA, 1980) and *Ex Parte Hozumi*, 3 U.S.P.Q.2d 1059. Moreover, it is respectfully submitted that even if the Examiners actions were based upon "improper Markush grouping", the restriction would still be improper based upon the logic and holding of *In re Harnisch*.

c) The M.P.E.P. does not Overrule Statute or Judicial Precedent

As a preliminary matter, Applicant submits that it is self-evident that the Manual of Patent Examining Procedure (M.P.E.P.) must be consistent with, and not contravene, statute or judicial precedent. It is further submitted that any part of the M.P.E.P. that is inconsistent with statute or judicial precedent is improper and must not be followed. Moreover, any part of the M.P.E.P. that is used to support an argument must be used properly. The M.P.E.P. should not be quoted outside of its intended context.

d) The Subject Matter of the Present Controversy is Resolved by *In re Weber*

*In re Weber* holds that:

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*"It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to Restrict an Application to one of several claimed inventions when those inventions are found to be "independent and distinct". It does not, however, provide a basis to an examiner acting under the authority of the Commissioner to Reject a particular Claim on that same basis."*

*( In re Weber, 580 F.2d 455, 458, 198 U.S.P.Q. 328, \_\_ (CCPA, 1978))*

*"We hold that a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses." (emphasis added).*

*(In re Weber, 580 F.2d 455, 459, 198 U.S.P.Q. 328, \_\_ (CCPA, 1978))*

Accordingly, it is clear from *In re Weber* that the legal issue of whether or not The Office may impose a restriction requirement to a single claim has been decided against The Office. It is well settled that such a requirement violates 35 U.S.C. 112, where the applicant is statutorily entitled to claim his invention as he deems proper, notwithstanding 35 U.S.C. § 121. This is true whether or not the inventions are determined by The Office to be independent and distinct.

The reasoning supporting Denial of the petition dated July 28, 2004 appears to completely ignore this argument and the clear precedent of *In re Weber*. Instead the arguments in support of the Denial of the petition make reference to various sections of the M.P.E.P., none of which are on point. Accordingly, Applicant submits that the Denial of the petition is improper and that the Restriction Requirement should properly be withdrawn in view of the express holding of *In re Weber*.

e) Arguments Relying on M.P.E.P. § 803.02 are Off Point and Irrelevant

The Decision makes reference to M.P.E.P. § 803.02 which makes reference to *In re Harnisch* and *Ex parte Hozumi*. This section of the M.P.E.P. and these judicial decisions deal with the issue of "improper Markush grouping" and not with rejections for "misjoinder of invention" under 35 U.S.C. § 121. Accordingly, they are irrelevant to the issue to be decided – specifically whether a restriction requirement directed to a single claim is proper under 35 U.S.C. § 121. According to *In re Weber*, it is not proper to restrict a single claim under 35 U.S.C. 121.

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With respect to the restriction requirement under 35 U.S.C. § 121, *In re Harnisch* specifically stated clarified that:

*"It should also be clear from what we have said that we adhere to our holdings in In re Weber, supra, and In re Haas (Hass II), supra. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be reasonably construed to have such an effect. The "unity of invention" concept is not to be confused with the "misjoinder under 35 U.S.C. § 121" rejection employed in In re Weber. In Weber we dealt with the use of 35 U.S.C. § 121, which deals with restriction requirements to support the rejection of a single claim. Here we are concerned with the rejection of a single claim on the distinct ground that it is directed to an "improper Markush group". (Emphasis added)*

(*In re Harnisch*, 631 F.2d 716, 722, 206 U.S.P.Q. 300, \_\_ (CCPA, 1980)

Because *In re Harnisch* specifically states that it does not overrule *In re Weber* and that the two opinions deal with distinctly different legal issues, it was entirely improper for the Decision to ignore Applicants arguments which rely upon *In re Weber* and instead rely on precedent that is clearly off point. For this reason alone the Decision is fatally flawed.

¶ The Restriction Requirement Would Still Be Improper Even If Based Upon "Improper Markush Grouping"

i) *The Decision Ignores The Mandate of M.P.E.P. § 803.02*

Apparently quoting from M.P.E.P. § 803.02, the Decision states:

*"Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." In re Harnish 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility."*

(Decision at page 3)

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It is respectfully submitted that, the Decision misapplies M.P.E.P. § 803.02. Specifically, M.P.E.P. § 803.02 expressly states that it is acceptable for a Markush claim to include independent and distinct inventions. Moreover, the section mandates election practice and not restriction practice. For example M.P.E.P. § 803.02 expressly reads:

*"This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 V.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability."* (emphasis added)

(M.P.E.P. § 803.02)

Accordingly it is clear that the Decision misapplies the directives of M.P.E.P. § 803.02 and therefore the Decision is again fatally flawed at least for this reason. Moreover, it is clear from M.P.E.P. § 803.02 that the correct way to proceed with Applicant's claims is to issue an election, not a restriction, requirement if the Examiner is so inclined. It is noted that an election requirement is permissive and not mandatory. That is why the word "may" is underlined in the text quoted from M.P.E.P. § 803.02, above.

ii) *Understanding & Applying In re Harnisch*

It is respectfully submitted that the Decision improperly applies the holding of *In re Harnisch* to the facts and to the express teachings of the specification. For this reason alone, the Decision is again fatally flawed.

After quoting from M.P.E.P. § 803.02, the Decision proceeds to conclude (not reason) that the present claims do not share a common utility or a common disclosed

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structural feature that is essential to that utility. Specifically the Decision tersely concluded:

*"The 159 peptide nucleic acid sequences recited in claim 1 of the instant application do not share a common utility nor do they share any substantial structural feature, let alone any substantial feature disclosed as being essential to that utility. Probes which bind to a common structure, such as a selected chromosome, are not required to share a common structure. This is the case in the instant application and the Office has separated the probes based on their specific chromosome binding affinity (i.e. binding to chromosomes X, Y, 1,2,3,4,6, 7,8,9, 10, 11, 12, 16, 17, 18 or 20, etc...) and thus every invention has been placed within a group."*

(Decision at page 3)

With respect to what constitutes common utility, *In re Harnish* expressly states:

*"Over thirty years ago this court decided In re Jones, 34 CCPA 1150, 162 F.2d 479, 74 USPQ 149 (1947), reversing an "improper Markush group" rejection of claims to chemical compounds which were [\*722] growth-regulating compositions for plants, fungicides, and insecticides. Notwithstanding their various properties, the court found all of the compounds included in the claims were plant growth stimulants, thus having a common function. The court noted that in any Markush group the compounds "will differ from each other in certain respects." It laid down the proposition, with which the PTO agrees in its M.P.E.P., that in determining the propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components." (emphasis added)*

(*In re Harnish*, 631 F.2d 716, 722, 206 U.S.P.Q. 300 \_\_\_\_ (CCPA, 1980))

From the foregoing it is clear that The Office should not, when considering the appropriateness of Markush groupings, focus on trivial distinctions but must consider the compounds, and their associated functions, as a whole.

This position seems to also be supported by M.P.E.P. § 2173.05(h) which reads:

*"The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly reasonable for their function in the claimed*



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*relationship, and it is clear from their very nature or from the prior art that all of them possess this property.” (emphasis added)*

(M.P.E.P. § 2173.05(h))

In the present patent application, applicants claim a PNA probe, a set of PNA probes, methods for using one or more of the PNA probes to determine human chromosomes as well as kits comprising one or more of the PNA probes. Thus, the common utility of the claimed subject matter is the determination of one or more human chromosomes. For example the specification reads:

*“The non-nucleic acid probes of this invention are suitable for detecting, identifying or quantitating human chromosomes X, Y, 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18 or 20, as well as 13/21 as a pair, in a sample or in the individual cells of the sample.”*

(Specification at page 21, lines 2-5)

That common utility was also demonstrated by the Examples and illustrated in the Figures. For Example, Figures 12A and 12B illustrate the simultaneous determination of chromosomes X, Y and 1. Thus, it is remarkable that The Office could conclude that there is no common utility for these probes where the specification so clearly demonstrates the common utility.

Furthermore, the Decision acknowledges that PNA probes are an art recognized class of molecule by stating:

*“With respect to the nature of the invention, the claimed probes are not traditional nucleic acids, they are PNA or Peptide-Nucleic acids and have been claimed as “Non nucleic acid probes.” The difference with a PNA is that the backbone is not a traditional sugar-phosphate nucleic acid backbone, but one that has peptide structures. PNA’s function like nucleic acids in that they contain a sequence of bases (usually traditional nucleotide bases) (what is termed in the claims as a probing nucleobase sequence) which is responsible for the hybridization of a PNA to DNA.*

Accordingly, it is clear that, contrary to the terse conclusions of the Decision, the PNA probes are an art recognized class of compounds (i.e. PNAs share the common

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structure that The Office clearly has recognized) that, in the present case, share a common utility that is supported by the specification. Accordingly the conclusions of the Decision are obviously erroneous.

It is respectfully submitted that conclusions of the Decision were made in error because the teachings of the present application were viewed narrowly and not considered as a whole. For example, the Decision arbitrarily places the probes into groups for individual chromosomes despite the fact that Applicants have clearly demonstrated in the specification that the probes can be combined in assays to simultaneously determine two or more human chromosomes. Thus, it is clear that The Office has arbitrarily taken a narrow view the subject matter of the present application and not considered it as a whole as required by *In re Harnisch*.

iii) *Conclusion*

In summary, it is clear that the Decision fails to embrace and follow the holdings of *In re Webber*, *In re Hass* or *In re Harnisch* as well as fails to follow the relevant sections of the M.P.E.P. To the extent The Office wishes to limit the Examiner's search obligations, election, not restriction, is the proper vehicle to effect that desired outcome (M.P.E.P. § 803.02). Thus, reconsideration of the restriction requirement issued in the Office Action dated July 18, 2001 and affirmed by the Decision is hereby requested.

**Fees**

The Office is hereby authorized to deduct the required fee for consideration of this petition, believed to be \$ 130.00, from Deposit Account No. 01-2213 (Order No. BP9806US-CP2).

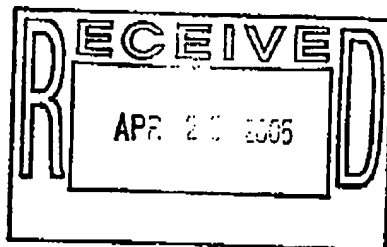
Respectfully submitted  
On behalf of Applicants,

  
Brian D. Gildea; Reg. No. 39,995

## UNITED STATES PATENT AND TRADEMARK OFFICE

APR 12 2005

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In re Application of  
Krishan L. Taneja  
Serial No. : 09/627,796  
Filed : 28 July 2000  
Attorney Dkt No. : BP9806US-CP2

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144 or 1.181 filed on 03 August 2004, to request withdrawal of the restriction requirement. The delay in acting on this petition is regretted.

**BACKGROUND**

A review of the file history shows that the application was filed on July 28 2000 with 45 claims (27 pages).

A requirement for restriction was mailed to applicants on September 21, 2001, requiring the restriction of the 45 claims to one of eighteen inventions under 35 U.S.C.

121. The claims were restricted as follows:

Groups I-V, VII, IX XI-XVI, claims 1-15, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosomes X, Y, 1, 2, 3, 6, 8, 10, 11, 12, 16, 17 and 18, respectively, and methods and kits for detecting, identifying, or quantitating said human chromosome in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6;

Group VI, claims 1-16, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome 4 and methods and kits for detecting, identifying, or quantitating human chromosome 4 in a sample, classified in class 536, subclass 23.1 and 435, subclass 6,

Group VIII, claims 1-15, 17, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome 7 and methods and kits for detecting, identifying, or quantitating human chromosome 7 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6;

Group X, claims 1-15, 18, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome 9 and methods and kits for detecting, identifying, or quantitating human chromosome 9 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6;

Group XVII, claims 1-15, 19, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome 20 and methods and kits for detecting,

identifying, or quantitating human chromosome 20 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6;

Group XVIII, claims 1-15, 20-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome pair 13/21 and methods and kits for detecting, identifying, or quantitating human chromosome pair 13/21 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

The examiner stated that the reasons for the restriction were based upon the following:

The inventions are distinct, each from the other because of the following reasons: Each group is directed to [peptide] nucleic acid sequences that identify or detect a different human chromosome. Each of the sequences are structurally and functionally different from each other. That is structurally, the sequences comprise a different sequence(s) of nucleotide bases, thus resulting in unique sequences. Functionally, the sequences are different in that they identify or detect different chromosome...

Applicants' traversal of the above restriction requirement on a number of different bases was not found persuasive by the office.

## DISCUSSION

Applicants petition under 37 C.F.R. 1.144 or 1.181, to withdraw the restriction requirement. Applicants complete argument supporting applicants position that the previous restriction requirement be withdrawn, is acknowledged.

With respect to the nature of the invention, the claimed probes are not traditional nucleic acids, they are PNA or Peptide-Nucleic acids and have been claimed as "Non nucleic acid probes." The difference with a PNA is that the backbone is not a traditional sugar-phosphate nucleic acid backbone, but one that has peptide structures. PNA's function like nucleic acids in that they contain a sequence of bases (usually traditional nucleotide bases) (what is termed in the claims as a probing nucleobase sequence) which is responsible for the hybridization of a PNA to DNA. Thus it is the nucleobase sequence that controls the function and specificity of PNAs (see specification page 6, lines 25-29).

Applicants traverse the present restriction requirement as being clearly contrary to the express holding of *In re Weber*. Applicants submit that *In re Weber* holds that:

It is apparent that 121 provides the Commissioner with the authority to promulgate rules designed to Restrict an Application to one of several claimed inventions when those inventions are found to be "independent and distinct". It does not, however, provide a basis to an examiner acting under the authority of the Commissioner to Reject a particular Claim on that same basis. *In re Weber*, 580 F.2d 455, 458, 198 U.S.P.Q. 328, \_\_ (CCPA, 1978) We hold that a rejection under 121 violates the basic right of the applicant to claim his invention as he chooses (emphasis added). *In re Weber*, 580 F.2d 455, 459, 198 U.S.P.Q. 328, \_\_ (CCPA, 1978)

Applicants thus submit that the legal issue of whether or not the Office may impose a restriction requirement to a single claim has been decided against the Office and that it is well settled that such a requirement violates 35 U.S.C. 112, where the applicant is statutorily entitled to claim his invention as he deems proper, notwithstanding 35 U.S.C. 121. Applicants further submit that this is true whether or not the inventions are determined by the Office to be independent and distinct.

Applicants' attention is drawn to the MPEP 803.02, which states:

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

The 159 peptide nucleic acid sequences recited in claim 1 of the instant application do not share a common utility nor do they share any substantial structural feature, let alone any substantial feature disclosed as being essential to that utility. Probes which bind to a common structure, such as a selected chromosome, are not required to share a common structure. This is the case in the instant application and the Office has separated the probes based on their specific chromosome binding affinity (i.e. binding to chromosomes X, Y, 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18 or 20, etc...) and thus every invention has been placed within a group.

As each of the 159 independent and distinct peptide nucleic acid sequences listed in claim 1 and thus the claimed PNA probes comprising said sequences do not share a common utility nor a substantial structural feature disclosed as being essential to said utility, it is thus proper for the Office to set forth a restriction requirement within a claim. Further, election of species practice is not required.

Because the embodiments are listed in the alternative, applicants can achieve coverage of the full scope of the claims by the appropriate filing of divisional applications, without the loss of scope of the claimed invention.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

It is noted that the elected group under examination is directed to 7 independent and distinct peptide nucleic acid sequences and said 7 sequences is in the range of 1-10 as per 1192 O.G. 68 (November 19, 1996), Examination of Patent Applications Containing Nucleotide Sequences.

Applicants further note the similar classification (i.e. Class 536, subclass 23.1 and Class 435, subclass) of each Group that the Examiner has argued is a separate invention.

Applicants submit that based upon the similar classification, for purposes of a search, there is no additional burden placed upon the office since the same class and subclass must be searched and no additional Class or subclass must be searched.

Applicants' argument regarding the additional search burden imposed by the examination of all of the claims is acknowledged, however, not found persuasive. The mere similar classification of clearly different inventive subject matter is not a reason for maintaining said subject matter together. This can be seen by the number of clearly different inventions that can be found in the same class and subclass, such as class 536, subclass 23.1, in which any peptide nucleic acid probe would be classified. Additionally each peptide nucleic acid sequence must be searched independently of other peptide nucleic acid sequences in a number of different peptide nucleic acid databases in addition to any class/subclass searches.

Finally applicants take the position that said claims are generic and use proper Markush format.

Applicants' attention is again directed to the MPEP section 803.02 which deals with the treatment of Markush-Type claims which list alternatives having a common core structure and function:

If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.

Clearly this is not the situation in the instant application, as claim 1, the subject of the current petition to withdraw the restriction requirement contains at a minimum 159 independent and distinct peptide nucleic acid sequences.

As discussed above, the 159 peptide nucleic acid sequences listed in claim 1 lack a common structural feature essential to the common utility and therefore election of species practice is not required.

Thus applicants' complete argument supporting applicants position that the previous restriction requirement be withdrawn, is acknowledged, however not found persuasive.

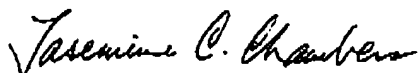
## DECISION

For these reasons, the Renewed Petition under 37 C.F.R. 1.144 and 1.181 to request withdrawal of the restriction requirement is **DENIED**.

The application will be forwarded to the examiner to consider the response filed 9/8/2004.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.



Jasmine Chambers  
Director, Technology Center 1600.